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IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF UTAH, CENTRAL DIVISION

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GELT TRADING, LTD., a Cayman Islands  
limited company,

Plaintiff,

v.

CO-DIAGNOSTICS, INC., a Utah  
Corporation, DWIGHT EGAN, JAMES  
NELSON, EUGENE DURENARD,  
EDWARD MURPHY, RICHARD SERBIN,  
REED BENSEN, BRENT SATTERFIELD,

Defendants.

Case No. \_\_\_\_\_

**CLASS ACTION COMPLAINT  
(PROPOSED CLASS ACTION)**

JURY DEMANDED

GELT TRADING, LTD. (“Gelt” or “Lead Plaintiff”), by and through its undersigned counsel, and on behalf of itself and all similarly situated plaintiffs, and for its Class Action Complaint against the Defendants CO-DIAGNOSTICS, INC. (“Co-Diagnostics” or “Company”),

DWIGHT EGAN, JAMES NELSON, EUGENE DURENARD, EDWARD MURPHY, RICHARD SERBIN, REED BENSON, and BRENT SATTERFIELD, hereby states as follows:

### **INTRODUCTION**

1. As the Covid-19 global pandemic began to spread to the United States, government and public health officials on the state and federal levels moved quickly to establish strategies to prevent the disease from devastating the country. Universally, those government strategies were predicated on establishing effective systems for mass testing of the U.S. population for the Covid-19 virus.

2. Fast, accurate, and readily accessible testing for Covid-19 provides government officials with crucial health information and data needed to combat the pandemic. It allows them to assess, in real-time, outbreaks of the virus and to take appropriate policy actions—such as quarantining and social distancing measures intended to prevent further mass transmission. And it allows them to allocate and, if necessary, seek resources to ensure that our public and private health systems can appropriately provide care for Covid-19 patients who require medical intervention and treatment.

3. To be sure, the ingenuity and industriousness of American enterprise has been integral to country's response to the Covid-19 pandemic. Health officials have worked closely with U.S. and international medical and pharmaceutical companies to develop Covid-19 tests, to seek potential therapeutics for the virus, and to ultimately obtain a vaccine. And many American companies have stepped up to this tremendous challenge, working with government counterparts to mitigate and hopefully end this pandemic.

4. There are, however, some companies and corporate executives who have sought to unfairly exploit this novel pandemic for their financial gain—including by, among other things, misleading the public about the efficacy of their products in combatting the pandemic. Defendant Co-Diagnostics is one of those companies.

5. As explained in greater detail below, Co-Diagnostics, its directors and officers—including PhD-level scientists who should know better—made continual, knowing and willful

misstatements about their main product, a Covid-19 diagnostic test, to pump up the price of Co-Diagnostics' stock while the officers and directors exercised low priced options and dumped their stock into the market. Their fraudulent misstatements, and disregard for the basic scientific principles that make their falsity of their statements clear in retrospect, cost investors to lose millions of dollars.

6. Unlike many securities fraud cases, the Co-Diagnostics fraud is blunt and simple to understand. Early in the Covid-19 pandemic, drug companies were racing to create an accurate diagnostic test for the virus that had quick response times. Co-Diagnostics seemingly won that race. Co-Diagnostics announced that it had received regulatory clearance to sell its tests in the European Community on February 24, 2020—the first company in the world to receive this clearance. Then, on April 6, 2020 the company announced that it had received emergency use authorization for its tests from the U.S. Food and Drug Administration.

7. Throughout this time and thereafter, Co-Diagnostics, its Chief Technology Officer, and its other officers and directors made unequivocal statements to the market *that its Covid-19 tests were 100% accurate*—a staggering claim that appeared to set Co-Diagnostics apart from other competitors developing Covid-19 tests. As was later revealed, however, this was not true: Co-Diagnostics' Covid-19 tests are materially less than 100% accurate – a discrepancy that can have momentous adverse consequences if Co-Diagnostics' tests are used on a widespread basis, as intended.<sup>1</sup> Nonetheless, Co-Diagnostics' market-first test, together with its claims that its tests were perfectly accurate, allowed Co-Diagnostics to sign lucrative contracts with state governments in the U.S. and governments around the world.

8. As a result of this misrepresentation and the influx of taxpayer dollars to Co-Diagnostics, the company's stock soared—until it crashed. The crash came when Co-Diagnostics

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<sup>1</sup> As stated herein, diagnostics tests that are even slightly less than 100% accurate in clinical testing can have extraordinary public health consequences when it comes to practical testing accuracy in a field setting. For example, if a diagnostics test has a 98% “specificity” and “sensitivity” rate (two metrics that factor into a test's accuracy), the practical effect is that 1 in 3 tests will return false positive results for Covid-19. For this reason, it is critical that market leaders in this area have nearly perfect accuracy metrics in clinical settings.

began acting evasively about its Covid-19 tests' true accuracy and regulatory authorities contradicted claims made by Co-Diagnostics about the accuracy of diagnostic tests.

9. Prior to the release of the news undermining Co-Diagnostics' false claims of 100% accuracy, Co-Diagnostics' stock enjoyed an all-time high stock price of \$29.72 per share and a market capitalization of over \$800 million. This was quite an accomplishment for a company that was at risk of being delisted from the exchange on New Year's Day, 2020, when it was trading at \$.91 and was worth less than \$25 million. Just a year ago Co-Diagnostics was in danger of being delisted from NASDAQ on July 2, 2019 because it was consistently trading under a dollar; now it was trading at thirty times that. Co-Diagnostics officers and directors were poised to make a fortune on the inflated stock price.

10. On May 14, 2020, Co-Diagnostics was set to announce its first quarter earnings after markets closed. Before the markets closed and before the earnings call, however, news outlets reported that Co-Diagnostics was reticent to participate in U.S.-based testing to verify its accuracy claims.

11. As public reports casting doubt on Co-Diagnostics claims of 100% accuracy began to circulate, the stock declined rapidly. After negative information about the Co-diagnostics' tests began to be reported, the stock went from its daily high of \$29.52, down to \$20, and hit an intra-day low of \$18.35 before closing at \$22.13. The losses on May 14, 2020, were so sudden that the stock stopped trading at one or two periods during the day, and its losses may have been higher but for NASDAQ's intervention.

12. After markets closed and with this information in hand, Co-Diagnostics issued an earnings report for the first quarter of 2020 and held a call that commented on the company's future prospects. On the call, CEO Dwight Egan offered a glowing report explaining that the company had sold 6 million tests, and had already purchased components to manufacture an additional 20 million tests that were already ordered by customers.

13. On the call, neither Egan nor its Chief Financial Officer, Reed Benson, made mention of the public statements made by third parties relating to the tests' accuracy. Notably,

Chief Science Officer, and inventor of Co-Diagnostics' technology, Brent Satterfield, Ph. D., was absent from the call and did not address the allegations after boasting to the market about Co-Diagnostics' Covid-19 testing accuracy in press releases in the weeks leading to the company's earnings announcement.

14. That evening, in response to other drug companies' widely-reported test accuracy struggles, financial news services began reporting that the U.S. Food and Drug Administration announced publicly that no Covid-19 test is 100% accurate. Of course, this announcement by the FDA undermined Co-Diagnostics' claims about its tests' perfect accuracy.

15. When markets opened on May 15, 2020, the stock slid to \$15.80 per share. The stock never rebounded, and today trades at severely reduced volume for between \$15 and \$16 per share, with expectations that the stock will trend lower due to the company's product not being what it promised, public skepticism, and the realization by investors that Co-Diagnostics was a flash-in-the-pan company that achieved astronomical gains by deceiving the public while it was wrestling with an unprecedented global pandemic.

16. During this time, and with a cloud of doubt hanging over the company's claims of accuracy, Co-Diagnostics' directors and officers have been rapidly exercising stock options for pennies per share and immediately selling their shares into the market reaping millions of dollars from the fraud-inflated price of the stock. The Officers and Directors, knowing the truth of the company's products and its future prospects, are taking their profits at cost to the public markets before the company inevitably becomes a penny stock once more. The investing public at large does not have the luxury of purchasing its shares at pennies on the dollar. Investors who believed Co-Diagnostics claims of 100% accuracy have lost hundreds of millions of dollars as a result of Co-Diagnostics' blatantly fraudulent statements to the investing public.

17. This class action, therefore, seeks to hold Co-Diagnostics and its executives to account for their misrepresentations on behalf of defrauded investors.

#### **JURISDICTION AND VENUE**

18. The Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1332 because the

claims asserted are between citizens of a foreign nation and citizens of this state. The Court also has original jurisdiction pursuant to 28 U.S.C. § 1331, because questions of federal securities law predominate the asserted claims.

19. The Court has personal jurisdiction because the Defendants committed tortious acts within this judicial district and Defendants reside in Utah.

20. Pursuant to 28 U.S.C. § 1391, venue is proper in this Judicial District because a substantial part of the events or omissions giving rise to the claim occurred in this Judicial District.

21. All conditions precedent have occurred, been performed or have otherwise been waived.

22. Gelt has retained the undersigned law firms to prosecute this action and has agreed to pay the law firm a reasonable fee for its services, plus out of pocket expenses.

### **PARTIES**

23. The Plaintiff, Gelt, is a Cayman Islands limited company.

24. Defendant, Co-Diagnostics, Inc. is a Utah Corporation with offices in Salt Lake City, Utah.

25. Defendants, Dwight Egan, James Nelson, Eugene Durenard, Edward Murphy, Richard Serbin, Reed Bensen, and Brent Satterfield are directors and/or officers of Co-Diagnostics. Upon information and belief, each individual defendant resides and conducts business in the State of Utah.

26. The Defendants named above, other than Co-Diagnostics, are referred to herein as the “**Individual Defendants**.” During the Class Period, the Individual Defendants, as senior executive officers and/or directors of Co-Diagnostics, were privy to confidential and proprietary information concerning Co-Diagnostics, its operations, finances, financial condition and present and future business prospects. The Individual Defendants also had access to material adverse non-public information concerning Co-Diagnostics, as discussed in detail below. Because of their positions with Co-Diagnostics, the Individual Defendants had access to non-public information about its business, finances, products, markets and present and future business prospects via access

to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and/or board of directors meetings and committees thereof, and via reports and other information provided to them in connection therewith. Because of their possession of such information, the Individual Defendants knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

27. The Individual Defendants are liable as direct participants in the wrongs complained of herein. In addition, the Individual Defendants, by reason of their status as senior executive officers and/or directors, were “controlling persons” within the meaning of Section 20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to and did, directly or indirectly, control the conduct of Co-Diagnostics’s business and participated in the conduct alleged below.

28. The Individual Defendants, because of their positions with Co-Diagnostics, controlled and/or possessed the authority to control the contents of its reports, press releases and presentations to securities analysts and through them, to the investing public. The Individual Defendants were provided with copies of the Company’s reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, the Individual Defendants had the opportunity to commit the fraudulent acts alleged herein.

29. As senior executive officers and/or directors and as controlling persons of a publicly traded company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, and was, and is, traded on the NASDAQ Exchange and governed by the federal securities laws, the Individual Defendants had a duty to disseminate promptly accurate and truthful information with respect to Co-Diagnostics’ financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings and present and future business prospects, to correct any previously issued statements that had become

materially misleading or untrue, so that the market price of Co-Diagnostics' securities would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

30. The Individual Defendants are liable as participants in a fraudulent scheme and course of conduct which operated as a fraud or deceit on purchasers of Co-Diagnostics publicly traded securities by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived the investing public regarding Co-Diagnostics's business, operations and management and the intrinsic value of Co-Diagnostics securities; and (ii) caused Lead Plaintiff and members of the Class to purchase Co-Diagnostics publicly traded securities at artificially inflated prices.

#### **LEAD PLAINTIFF'S CLASS ACTION ALLEGATIONS**

31. Lead Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all those who purchased the securities of Co-Diagnostics between February 25, 2020 and May 15, 2020, (the "Class Period") inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

32. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Co-Diagnostics stock was actively traded on the NASDAQ Exchange. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believe that there are hundreds or thousands of members in the proposed Class. For example, on the last two days of the class period alone almost 75 million shares of Co-Diagnostics were bought and sold, meaning that each issued and outstanding share of stock changed hands an average of three times on those days alone. Record owners and other members of the Class may be identified from records maintained by Co-Diagnostics or its transfer agent and may be notified of the pendency of this



action by mail, using the form of notice similar to that customarily used in securities class actions.

33. Lead Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law complained of herein. Lead Plaintiff purchased shares prior to May 14, when the truth about the tests' accuracy began to be revealed, at a price much higher than the price at which the stock traded after the truth of the tests' accuracy was publicly revealed.

34. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

35. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- (a) whether the federal securities laws were violated by Defendants' acts as alleged herein;
- (b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business and operations of Co-Diagnostics;
- (c) whether the prices of Co-Diagnostics's publicly traded securities were artificially inflated during the Class Period; and
- (d) to what extent the members of the Class have sustained damages and the proper measure of damages.

36. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

### **FACTUAL ALLEGATIONS COMMON TO ALL COUNTS**

#### **I. History of Co-Diagnostics and Historical Market Performance**

37. Co-Diagnostics, Inc. was formed on April 18, 2013, as a Utah corporation. Upon

information and belief, the company was formed to monetize the DNA-testing technology developed by Biomedical Engineering Ph.D. Brent Satterfield.

38. Defendant Egan, Co-Diagnostics' current CEO, joined the company as an officer and director in April 2013.

39. Defendant Benson has served as the company's CFO, board secretary, and as a director of Co-Diagnostics since 2014.

40. After several years of operating as a "start-up" in the private sector, Co-Diagnostics filed an SEC Form S-1 Registration Statement on April 28, 2017, with an attached prospectus.

41. The prospectus described that the company owned proprietary technology that enabled it to do DNA testing for diagnostic purposes.

42. For example, the prospectus stated that, as of 2017, Co-Diagnostics' primary source of revenue was from selling diagnostics tests for Zika Virus, Tuberculosis, Hepatitis B, Hepatitis C, Malaria, Dengue Fever, and HIV. Its customers were primarily located in the Caribbean, in Central and South America, in North America, and in India.

43. The company forecasted that it would be authorized to sell Tuberculosis, Hepatitis B, and Hepatitis C tests in the European Union in 2018 and 2019.

44. The prospectus admits that beyond 2019, the company did not have a plan for further research and development or any target diseases that it was aiming to create diagnostic tests for, but anticipated to selling tests "based on need and regulatory barriers" in the United States.

45. The stock first listed on the NASDAQ exchange on July 12, 2017 and opened at \$6. The stock slowly slid down in price to become a "penny stock" trading at less than \$1 per share for extended periods. The stock closed on December 31, 2019 at \$0.8952 per share.

46. Co-Diagnostics was in danger of being delisted from the NASDAQ, which requires that companies not trade below \$1.00 per share to continue being listed on the exchange.

## **II. Co-Diagnostics, Without Direction or Strategy, Stumbles Into Its Best Possible Opportunity as the World Begins to Reel from the Covid-19 Pandemic**

47. As is now common knowledge, in late 2019, a new virus began to spread rapidly

through the population in Wuhan, China. That virus, which has become known as Covid-19, has ravaged the world's economies and healthcare systems, and has resulted in millions of infections and hundreds of thousands of deaths. Covid-19 is a virus and it can be detected by DNA-based testing. Because Co-Diagnostics expertise is DNA-based testing, the world's need for accurate Covid-19 testing—to help control the spread of the virus—presented a unique opportunity to Co-Diagnostics to use its technology and expertise to earn money.

48. According to Co-Diagnostics, it began developing Covid-19 tests rapidly using a technology called CoPrimer, which was developed and patented by Satterfield before the outbreak. Based on public reports, Co-Diagnostics used the CoPrimer technology to develop a Covid-19 diagnostics test within one week.

49. CoPrimer allegedly worked so well that Co-Diagnostics, despite its relatively small size, became the first company in the world to obtain the prestigious CE marking for its Covid-19 tests. The CE certification mark indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area.

50. Co-Diagnostics announced on February 24, 2020, that it had received regulatory approval to sell in the European Community. It was the first U.S. company to receive approval for the export to Europe of Covid-19 test kits.

51. Co-diagnostics' stock began to rise on the news. The stock traded at over \$15 per share at the end of February 2020, and at over \$17 per share in early March.

52. On April 6, 2020, Co-Diagnostics became the first company to receive approval from the U.S. FDA for its Covid-19 tests under an Emergency Use Authorization, which permitted Co-Diagnostics' tests to be used by certified clinical laboratories in the U.S. for the diagnosis of Covid-19.

53. The stock, which in the weeks after the CE announcement had settled to \$8 per share, began to climb again.

54. Co-Diagnostics rushed its product to market because it had many larger competitors who were also hurrying to get an accurate diagnostic test to market.

### III. Co-Diagnostics Makes Material Misrepresentations About Its Covid-19 Tests, Sending Its Stock Soaring—And Then Crashing

55. After Co-Diagnostics obtained its certifications, it began selling millions of dollars' worth of Covid-19 tests to 50 countries and more than 12 states in the U.S. The stock continued to climb.

56. During this time Co-Diagnostics was able to obtain lucrative contracts to provide testing to states and foreign countries. For example, Co-Diagnostics was going to provide the majority of the tests for a \$5 million contract with the state of Utah that ran from March 31, 2020 through May 30, 2020. Co-Diagnostics was also to provide tests for a contract with Iowa totaling \$26 million for approximately 540,000 testing kits.

57. Not all news was good, however. On April 30, 2020, The Salt Lake Tribune published an article titled "'This is a Potential Public Health Disaster': COVID-19 results from TestUtah.com are raising questions." The article questioned the accuracy of Co-Diagnostics tests being used at sites run by TestUtah.com.

58. Satterfield was quoted in the article, reassuring the public that the alleged inaccuracies were due to "population differences".

59. In response to the Tribune's questions, Satterfield reassured the market that Co-Diagnostics' tests were between 99.52% and 100% accurate in unspecified FDA and European studies. Satterfield also said the company had received no complaints from anyone Co-Diagnostics supplied tests to in 50 countries.

60. On May 1, 2020, to allay public health and investor concerns, Co-Diagnostics issued a press release titled: "Co-Diagnostics, Inc. Releases COVID-19 Test Performance Data: Consistently Demonstrates 100% Sensitivity and 100% Specificity Across Independent Evaluations". The press release unequivocally stated that Co-Diagnostics Covid-19 tests were 100% accurate based on data gathered from across the world:

Co-Diagnostics, Inc. (**Nasdaq:CODX**) (the Company), a molecular diagnostics company with a unique, patented platform for the development of diagnostic tests, today released COVID-19 test

performance data demonstrating 100% sensitivity and 100% specificity, the metrics used to determine accuracy in molecular diagnostics testing.

The data being released comes from independent evaluations of the performance of the Company's COVID-19 test in the field. These evaluations were conducted in Mexico by the Mexican Department of Epidemiology ("InDRE"), India, and elsewhere in the US and abroad. Each study concluded 100% concordance for both specificity and sensitivity.

61. In the press release, Satterfield did not mention that the tests might be less than 100% accurate—abandoning his recognition that the tests were between 99.52% and 100% accurate. Instead, Satterfield insisted that Co-Diagnostics' tests were 100% accurate based on the experimental data:

In remarking on the test's favorable limit of detection (LOD) results in the evaluations, Brent Satterfield, PhD said, "In diagnostics, the limit of detection or LOD is a single metric that helps inform the key metrics of sensitivity and specificity but is not relevant as a stand-alone data point. Other metrics that are important are availability, ease of use and throughput. In countries where we have been evaluated against other tests, *we have consistently and repeatedly achieved 100% clinical sensitivity and specificity and you can't do better than that.*"

(emphasis added).

62. While in most situations, 99.5% accuracy and 100% accuracy are functionally equivalent, in diagnostic testing of diseases with a low population saturation, the difference can dramatically affect whether a test has any value to public health officials.

63. For example, in Utah Covid-19 testing has fairly consistently resulted in only 5% of apparently-symptomatic test subjects testing positive for Covid-19. In other words, for every 1,000 tests, only about 50 people test positive. However, even if Co-Diagnostics tests were 99.5% accurate—and it appears they are much less accurate than that—as described in greater detail below, there would be five people who did not have the test but who tested positive. In other words, one in ten people who tested positive would not have the disease. At only slightly lower accuracy rates, the test becomes essentially worthless for public health testing and tracing.

64. In practice, Co-Diagnostics results seemed to be even worse than these result rates would suggest. For example, the April 30th Tribune article reported that Co-Diagnostics tests being used by TestUtah.com resulted in only a 1% to 2% positive test rate even in symptomatic patients, suggesting that Co-Diagnostics tests were only accurately reporting half of the Covid-19 infections, suggesting an accuracy rate even worse than the 99.5% that Co-Diagnostics initially claimed and infinitely worse than the 100% accuracy rate Co-Diagnostics began to tout in early May.

65. The market, however, accepted Co-Diagnostics false claims of 100% accuracy -- resulting in a boon to the company's share price. For example, the following publications repeated Co-Diagnostics claims, amplifying their effect on the market:

- “**Co-Diagnostics (CODX)** said Friday its coronavirus test has proven 100% accurate in field testing — leading CODX stock to rocket.” Allison Gatlin, Investor's Business Daily, “Coronavirus Test Maker Soars As Its Diagnostic Proves 100% Accurate.”

1.

- “Co-Diagnostics says coronavirus test shows spotless sensitivity data in independent evaluations” Proactiveinvestors.com
- “Co-Diagnostics Is a Smart Way to Play Coronavirus Testing: The company's tests are reportedly 100% accurate in at least three countries” Louis Navellier, Investorplace.com

66. Co-Diagnostics did not release any clarifying statement about the accuracy of its test and has not addressed the allegations in public filings or press releases.

67. Co-Diagnostics' stock continued to rise in May, as investors anticipated an earnings announcement and financial report for the first quarter of 2020 on May 14, 2020 after markets closed.

68. Co-Diagnostics' plan to repress negative reports about its tests seemed to work. On May 14, 2020, the stock reached an all-time high of \$29.72, an extraordinary climb from its \$0.8952 year-end 2019 price.

69. However, around that same time, Co-Diagnostics' claims of test accuracy became

unsustainable.

70. In the late morning and early afternoon of May 14, 2020, third parties revealed startling information about Co-Diagnostics' allegedly 100% accurate test.

71. The Salt Lake Tribune reported that TestUtah.com, which used tests developed by Co-Diagnostics, "declined to join other major Utah labs in a joint experiment to confirm one another's quality." Moreover, The Salt Lake Tribune revealed that TestUtah's tests [by Co-Diagnostics] "have a higher 'limit of detection' — that is, they require more of the virus to trigger a positive result — than most other coronavirus tests approved for sale in the U.S., according to an analysis by the life sciences publication BioCentury." This meant that Co-Diagnostics tests were likely to have a much higher false negative reporting rate, meaning that potentially thousands of infected people were inaccurately told that they did not have the disease, an observation that was consistent with earlier concerns about TestUtah's lower rate of positive test results.

72. The Tribune article also expressed concern relating to TestNebraska.com and TestIowa.com, testing services that also used Co-Diagnostics tests.

73. Also on May 14th, Iowa Governor Kim Reynolds issued a public statement saying, "I'm pleased to announce that the State Hygienic Lab completed the Test Iowa validation process yesterday, achieving high ratings of 95 percent accuracy for determining positives and 99.7 percent accuracy for determining negatives." These results did not comport with statements previously made by Co-Diagnostics on May 1, 2020.

74. In fact, Satterfield himself has recently confessed that the lower positive rates for Co-Diagnostics' tests "has certainly got all of us scratching our heads a bit," and that the tests will correctly identify 95% of true positive results—a massive discrepancy from Co-Diagnostics' representations of 100% accuracy given that the tests are intended to be administered among hundreds of thousands or even millions of people

75. Based on the release of third party information casting serious doubt as to Co-Diagnostics' bold claims of 100% accuracy, the stock price began to fall, closing the day at \$22.13 after hitting an intra-day low of \$18.35, a greater than 38% decrease in price within hours.

76. At that point, Co-Diagnostics could have, but did not, revise its claims of 100% test accuracy, given that Co-Diagnostics released earnings and first quarter 2020 financials to the public after hours and had a scheduled investor call for the same evening.

77. Co-Diagnostics did report that it achieved record sales and that the start-up had finally, after nearly 7 years, reached profitability; however, it did not address the testing accuracy or sensitivity allegations or correct Satterfield's prior statements about tests being 100% accurate.

78. Rather, the call was described by The Gazette, a Cedar Rapids, Iowa publication covering TestIowa.com as sounding "more like Thanksgiving with drunk uncles — dogs were barking, people were swearing, and someone was moaning." The Gazette also accurately noted that "[n]one of Co-Diagnostics or Nomi Health's news releases about the Logix Smart tests have revealed how many tests have been sold, for how much, and so far all three testing initiatives in Iowa, Nebraska and Utah have been secretive about the tests and the results."

79. The same day, the United States FDA issued a press release about testing accuracy. Another, much larger drug company had created a diagnostic test for Covid-19 that was under increasing public scrutiny for apparent inaccuracy. The FDA announced to the public that "[t]he FDA looks at a variety of sources to identify and understand potential patterns or significant issues with the use of the Abbott test. *No diagnostic test will be 100% accurate* due to performance characteristics, specimen handling, or user error, which is why it is important to study patterns and identify the cause of suspected false results so any significant issues can be addressed quickly." (emphasis added).

80. Based on the multiple third party sources revealing serious problems that were known, or should have been known, in advance of May 14, 2020, the stock price further fell to just over \$15 per share when markets opened on May 15, 2020.

81. By May 20, 2020, a statistician, Zhiyuan Sun, wrote an article specifically about Co-Diagnostics' allegedly 100% accurate Covid-19 test. Sun explained:

In May, Co-Diagnostics announced its COVID-19 in vitro test had been found to have 100% accuracy, 100% specificity (likelihood of preventing a false-negative



error), and 100% sensitivity (likelihood of preventing a false-positive error), as per independent verification in laboratories across the world

....

### **The devil is in the details**

To start off, Co-Diagnostics came to the conclusion that its test was 100% effective on all three diagnostic dimensions (specificity, accuracy, and sensitivity) based on studies with small sample sizes. For example, laboratory testing of the Logix test kit conducted in Australia involved about 100 COVID-19-positive patients and 100 COVID-19-negative patients. With a sample size that small, a low error rate, say 1% to 2%, could be really hard to detect. In fact, the study itself explicitly stated that the test could in fact be between 96% to 98% effective, rather than 100%.

In addition, the testing environment is by no means indicative of the actual prevalence of COVID-19 in the population at this point in the pandemic. Among the test samples, 50% contained SARS-CoV-2, and obviously, at this point, nowhere near half the people in the world have been exposed to the coronavirus. "But wait a minute!" the intelligent reader might say. "Nothing in the world is perfect, so who cares if a test's results are off by 1% or 3%? Effectiveness of 97% is still nothing short of an A-plus. You're just being a devil's advocate, Zhiyuan!" Unfortunately, this is one of the cases where it is critical to pay attention to the devil in the details. In fact, a 1% or 3% error rate can render a *in vitro* test almost useless. Here's why.

Let us assume, for the sake of argument, the true sensitivity of Logix is 98%, and its true specificity is also 98%. In other words, the probability of the test delivering a false positive is 2%, and the probability of the test returning a false negative is also 2%. Both of these values are directly stated as being probable in studies citing Logix's range of effectiveness, and they are valid assumptions given that the test has not been fully vetted by the FDA or other regulators. It is also common knowledge that because there are not enough viral tests for the COVID-19, the number of people who have the virus is likely to be significantly higher than official figures. For example, it is estimated that up to 4.1% of the residents of Los Angeles County have COVID-19 antibodies. Let's use that 4.1% figure in our calculations as a measure of prevalence of COVID-19 (a lower prevalence would hurt the test even more). Assuming 1 million people are given the Logix test, 41,000 should test positive for an ongoing SARS-CoV-2 infection. However, if the test provides a false negative 2% of the time, only 98% of those 41,000 -- 40,180 -- would show up as positives.

On the other hand, out of the 959,000 people who were actually negative for the virus, a 2% error rate would yield 19,180 cases of false positives -- individuals who don't have the disease despite the test saying they do. All told, that makes 59,360 people getting positive results, but only 40,180 of them would actually be positive. That yields a predictive value of 67.7%.

In other words, if the Logix test only works as well as it does in this scenario -- and it's right 98% of the time -- there's still a **1-in-3** chance that the test will indicate you have COVID-19 even though you don't! As one can see, a 32.3% false-positive error rate isn't very good at all. This problem gets worse if we assume the same prevalence, but lower Logix's potential sensitivity and specificity estimates to 95% for both. In this scenario, the probability of getting a false positive increases to 55.2%! While the results are surprising, they nonetheless use the basics of conditional probability; here is a calculator in case you want to try it out for yourself. Furthermore, a recent New York University study on COVID-19 in vitro tests developed by **Abbott Laboratories** (NYSE:ABT) found them to be widely inaccurate and unacceptable for use in patients. Keep in mind, those tests were also promoted as having 100% sensitivity and 99.9% specificity in earlier investigations. Unfortunately, this just serves to highlight how difficult it is to develop an accurate test for diseases with a low rate of prevalence like COVID-19.

82. Co-Diagnostics knew that even a highly accurate test—such as 96%, 98%, or even 99%—was not the same, and not remotely as valuable, as a 100% accurate test. That is because having a 100% accurate test would have significantly distinguished Co-Diagnostics from other larger, more reputable competitors introducing Covid-19 tests into the marketplace. And also because the widespread administration of a Covid-19 test that is even minimally inaccurate can have highly adverse public health consequences. Co-Diagnostics knew this—and so it intentionally issued statements to the public to fend off truthful analysis and scientific skepticism about its supposed miracle test.

#### IV. Additional Scienter Allegations

83. As alleged herein, Defendants acted with scienter in that Defendants: knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Co-Diagnostics, their control over, and/or receipt and/or modification of Co-Diagnostics' allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information

concerning Co-Diagnostics, participated in the fraudulent scheme alleged herein.

84. Each of the Individual Defendants directly benefited from the fraudulent overstatement of the Company's technological capabilities in the form of at least the false inflation of their own stock and stock options, which Co-Diagnostics insiders have been cashing in on since the onset of the pandemic.

#### **V. Loss Causation/Economic Loss**

85. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct which artificially inflated Co-Diagnostics's stock price and operated as a fraud or deceit on Class Period purchasers of Co-Diagnostics stock by misrepresenting the Company's business success and future business prospects. Defendants achieved this façade of success, growth and strong future business prospects by misrepresenting the Company's financial statements, earnings and prospects. Later, however, when Defendants' prior misrepresentations and fraudulent conduct were disclosed and became apparent to the market, Co-Diagnostics stock fell precipitously as the prior artificial inflation came out of Co-Diagnostics' stock price. As a result of their purchases of Co-Diagnostics stock during the Class Period, Lead Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

86. The economic loss, *i.e.*, damages, suffered by Lead Plaintiff and other members of the Class was a direct result of Defendants' fraudulent scheme to artificially inflate Co-Diagnostics' stock price and the subsequent significant decline in the value of Co-Diagnostics's stock when Defendants' prior misrepresentations and other fraudulent conduct was revealed.

#### **VI. Applicability of Presumption of Reliance Fraud on the Market Doctrine**

87. The markets for Co-Diagnostics' common stock were open, well-developed and efficient at all relevant times. As a result of these materially false and misleading statements and omissions of material fact, Co-Diagnostics' publicly traded securities traded at inflated prices during the Class Period. Lead Plaintiff and other members of the Class purchased or otherwise

acquired Co-Diagnostics publicly traded securities relying upon the integrity of the market price of Co-Diagnostics publicly traded securities and market information relating to Co-Diagnostics and have been damaged thereby.

88. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Co-Diagnostics' common stock, by publicly issuing false and misleading statements and omitting disclosure of material facts necessary to make Defendants' statements, as set forth herein, not false and misleading. Said statements and omissions were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company, its business and operations, as alleged herein.

89. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused, or were a substantial contributing cause of, the damages sustained by Lead Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false or misleading statements about Co-Diagnostics' business, prospects and operations. These material misstatements and omissions had the cause and effect of creating in the market an unrealistically positive assessment of Co-Diagnostics and its business, prospects and operations, thus causing the Company's common stock to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in Lead Plaintiff and other members of the Class purchasing the Company's common stock at artificially inflated prices, thus causing the damages complained of herein.

90. At all relevant times, the market for Co-Diagnostics securities was an efficient market for the following reasons, among others:

(a) Co-Diagnostics common stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) as a regulated issuer, Co-Diagnostics filed periodic public reports with the SEC and NASDAQ;

(c) Co-Diagnostics regularly communicated with public investors via established market

communication mechanisms, including regular disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Co-Diagnostics was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

91. As a result of the foregoing, the market for Co-Diagnostics common stock promptly digested current information regarding Co-Diagnostics from all publicly available sources and reflected such information in the prices of the stock. Under these circumstances, all purchasers of Co-Diagnostics common stock during the Class Period suffered similar injury through their purchase of Co-Diagnostics common stock at artificially inflated prices and a presumption of reliance applies.

## **VII. No Safe Harbor**

92. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as “forward-looking statements” when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors which could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements were made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Co-Diagnostics who knew that those statements were false when made.

## **COUNT I** **Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants**

93. Lead Plaintiff repeats and realleges each and every allegation contained above as if

fully set forth herein.

94. During the Class Period, Defendants disseminated or approved the materially false and misleading statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

95. Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's common stock during the Class Period.

96. Lead Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Co-Diagnostics common stock. Lead Plaintiff and the Class would not have purchased Co-Diagnostics common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

97. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchases of Co-Diagnostics common stock during the Class Period.

**COUNT II**  
**Violation of Section 20(a) of the Exchange Act**  
**Against the Individual Defendants**

98. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

99. The Individual Defendants acted as controlling persons of Co-Diagnostics within the meaning of Section 20(a) of the Exchange Act as alleged herein. By reason of their positions as officers and/or directors of Co-Diagnostics, and their ownership of Co-Diagnostics stock, the

Individual Defendants had the power and authority to cause Co-Diagnostics to engage in the wrongful conduct complained of herein. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

**WHEREFORE**, Lead Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action and certifying Lead Plaintiff as Class representatives under Rule 23 of the Federal Rules of Civil Procedure and Lead Plaintiff's counsel as Lead Counsel;

B. Awarding compensatory damages in favor of Lead Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMAND**

Lead Plaintiff hereby demands a trial by jury.

DATED: June 15, 2020

**SMITH WASHBURN, LLP**

/s/ D. Loren Washburn  
D. Loren Washburn

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